

Exhibit M

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

- ☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
or
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
Or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Or
☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report
For the transition period from to
Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel
54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
American Depositary Shares, each representing one half of one ordinary share, par value €2 per share	NASDAQ Global Select Market
Ordinary shares, par value €2 per share	NASDAQ Global Select Market*
Contingent Value Rights	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2018 was:

Ordinary shares: 1,245,454,385

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. YES ☐ NO ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ No ☐.

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ No ☐.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer," "accelerated filer" or "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐

International Financial Reporting Standards as issued by

the International Accounting Standards Board ☒

Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

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If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐

No ☒.

*Not for trading but only in connection with the registration of American Depositary Shares representing such ordinary shares.

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ITEM 4. INFORMATION ON THE COMPANY

B.8. Production and raw materials

We have opted to manufacture the majority of our products in-house. There are three principal stages in our production process: the manufacture of active ingredients, the transformation of those ingredients into drug products or vaccines, and packaging those products.

Our general policy is to produce the majority of our active ingredients and principal drug products at our own plants in order to reduce our dependence on external suppliers. We also rely on third parties for the manufacture and supply of certain active ingredients, drug products and medical devices. Active ingredients are manufactured using raw materials sourced from suppliers who have been subject to rigorous selection and approval procedures, in accordance with international standards and our own internal directives. We have outsourced some of our production under supply contracts associated with acquisitions of products or businesses or with plant divestitures, or to establish a local presence to capitalize on growth in emerging markets. Our pharmaceutical subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See "Item 3. Key Information – D. Risk Factors – Risks Relating to Our Business".

At the start of 2017 we launched our "Global External Manufacturing" team, to enhance the way we manage relations with our third-party suppliers of finished products.

We also obtain active ingredients from third parties under collaboration agreements. This applies in particular to the monoclonal antibodies developed with Regeneron.

Our pharmaceutical production sites are divided into three categories:

- ◆ global sites, which serve all markets: located mainly in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectable products, and a number of our main solid-form products;
- ◆ regional sites, which serve markets at regional level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), giving us a strong industrial presence in emerging markets; and
- ◆ local sites, which serve their domestic market only.

Sanofi Pasteur produces vaccines at sites located in the United States, Canada, France, Mexico, China and India. The pharmaceutical site at Le Trait (France) also contributes to Sanofi Pasteur's industrial operations by making available its sterile filling facilities.

All of our production facilities are good manufacturing practice (GMP) compliant, in line with international regulations.

Our principal sites approved by the FDA are:

- ◆ the Biologics facilities in the United States (Allston, Framingham and Northborough), France (Lyon Gerland, Vitry-sur-Seine), Germany (Frankfurt) and Belgium (Geel);

- ◆ the Injectables facilities in France (Le Trait), Italy (Anagni), Ireland (Waterford), Germany (Frankfurt) and the United States (Ridgefield);
- ◆ the Pharmaceuticals facilities in France (Ambarès and Tours) and the United Kingdom (Haverhill);
- ◆ the Consumer Healthcare facilities in France (Compiègne) and the United States (Chattanooga); and
- ◆ the Vaccines facilities in France (Marcy l'Étoile and Le Trait, which handle filling and packaging of Fluzone® ID for the US market), the United States (Swiftwater) and Canada (Toronto).

Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and our strategic finished products (this is the case with Lovenox®, for example).

In May 2010, Genzyme's Allston facility in the United States entered into a consent decree with the US government following FDA inspections at the facility that resulted in observations and a warning letter raising Current Good Manufacturing Practices (CGMP) deficiencies.

The workplan was completed on March 31, 2016. The next step was a third-party certification process. In August 2017, the FDA conducted an inspection of the facility and delivered a favorable conclusion, following which certification was received on October 4, 2017.

The Allston facility is required to engage a third-party expert to audit its manufacturing operations for an additional period of at least five years.

More details about our manufacturing sites are given below at section "D. Property, Plant and Equipment".

B.9. Insurance and risk coverage

We are protected by four key insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our direct insurance company, Carraig Insurance DAC (Carraig).

These four key programs cover Property & Business Interruption, General & Product Liability, Stock and Transit, and Directors & Officers Liability.

Carraig participates in our coverage for various lines of insurance including Property & Business Interruption, Stock and Transit, and General & Product Liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover.

It sets premiums for our entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly verified and confirmed by independent actuaries.

Our Property & Business Interruption program covers all our entities worldwide, wherever it is possible to use a centralized

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ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

capital requirements. At year-end 2018, we held cash and cash equivalents amounting to €6,925 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements included at Item 18 of this annual report). As at December 31, 2018, €505 million of our cash and cash equivalents were held by our captive insurance and reinsurance companies in accordance with insurance regulations.

We run the risk of delayed payments or even non-payment by our customers, who consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies (see "Item 3.D. Risk Factors – 2. Risks Relating to Our Business – We are subject to the risk of non-payment by our customers"). Deteriorating credit and economic conditions and other factors in some countries have resulted in, and may continue to result in an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action. Over our business as a whole, the amount of trade receivables overdue by more than 12 months (which primarily consists of amounts due

from public sector bodies) decreased from €93 million as of December 31, 2017 to €61 million as of December 31, 2018 (see Note D.10. to our consolidated financial statements).

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights ("CVRs") and subsequently purchased CVRs in 2011. In 2012 following a tender offer initiated in September 2012 on the basis of the same corporate authorization, Sanofi purchased an additional 40,025,805 CVRs (for a total consideration of approximately \$70 million), followed by a further 10,928,075 CVRs (for approximately \$9 million) in 2013, 1,879,774 CVRs (for approximately \$1 million) in 2014, and none in 2015, 2016, 2017 and 2018. As of December 31, 2018, a total of 236,457,284 CVRs were outstanding out of the 291,313,510 issued at the time of the Genzyme acquisition.

At year-end 2018, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of €8 billion at December 31, 2018. For a discussion of our treasury policies, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."